## REMARKS

Claims 10, 11 and 20-38 are pending in the application. Claims 10, 20 and 23 have been cancelled without prejudice to presentation in future related applications. Claims 11, 21, 22, 24, 25, 27, 34, 35 and 38 have been amended. New claims 39 and 40 have been added.

The claims were revised, *inter alia*, to further improve clarity, to update dependency, and to specify particular types of cancer. Support for the amendments to claims 11, 21, 22, 24, 25, 27, 34, 35 and 38 and for new claims 39 and 40 can be found throughout the application as originally filed, including, for example, in the as-filed claims and paragraph [0033].[1]

No new matter has been added.

Upon entry of this amendment, claims 11 and 21, 22, 24-40 will be pending.

**IDS**

The Office notes that only one of the fourteen references cited in the IDS filed October 31, 2003 has been considered. According to the initialed Form 1149 returned by the Examiner it appears that the remaining thirteen references were not found by the Examiner when considering the IDS. Applicants will provide further copies of the thirteen references as part of a Supplemental IDS.

**Rejections under 35 U.S.C. §112, first paragraph (enablement)**

Claims 10, 11 and 20-38 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Although acknowledging that the specification was enabling for "a method for diagnosing bladder carcinoma, colon cancer, breast cancer or prostate cancer comprising detecting evidence of differential expression of sialophorin gene (SEQ ID NO: 1175) in a patient sample, wherein evidence of differential expression is detected by measuring the level of an expression product of sialophorin and wherein the expression product is a mRNA having a sequence of SEQ ID NO: 11 75, [the specification] does

1 Paragraph numbering is as set forth in United States Patent Application Publication 20020182586A1.

not reasonably provide enablement for the said method measuring a full complement of the mRNA sequence of SEQ ID NO:11 75 (sialophorin)."

Although Applicants respectfully disagree, solely in an attempt to advance the present application to allowance, the claims have been amended to remove the "full complement" language.

Applicants respectfully request withdrawal of the enablement rejection.

**Rejections under 35 U.S.C. §112, first paragraph (written description)**

Claims 11, 23 and 34-38 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Office alleges that "Applicants have not described nucleotide sequences at least 98% identical to SEQ ID NO: 1320, as well as complements thereof with sufficient particularity such that one skilled in the art would recognize that the Applicants had possession of the claimed invention." (Office Action, page 6). Because one of skill in the art would readily appreciate that the inventors had possession of the claimed invention at the time the present application was filed, Applicants respectfully traverse.

The specification provides sufficient written description for the pending claims as evidenced by the U.S. Patent and Trademark Office's own guidelines on the subject: Synopsis of Application of Written Description Guidelines, www.uspto.gov/web/menu/written.pdf ("Guidelines"). Example 14 of the Guidelines illustrates a hypothetical situation that mirrors the present case. Example 14 provides an example of a product by function claim, where the specification teaches that SEQ ID NO:3 and "variants that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction of A→B" are essential to the operation of the claimed invention. Example 14 then provides the following guidance to examiners:

> The specification indicates that the genus of [nucleic acids] that must be variants of SEQ ID NO:3 does not have substantial variation since all of the variants must possess the specified catalytic activity and must have at least 95% identity to the reference sequence, SEQ ID NO:3. The single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the

> presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO:3 which are capable of the specified [kinase-encoding] activity. One of skill in the art would conclude that applicant was in possession of the necessary common attributes possessed by the members of the genus.
> Conclusion: The disclosure meets the requirements of 35 USC §112 first paragraph as providing adequate written description for the claimed invention.

As in the Example 14 hypothetical, the present claims are drawn to a genus of molecules whose "variants must possess the specified activity and must have identity to" a reference sequence. In pending claims 11, 27 and 34, polynucleotides must have at least 98% sequence identity to SEQ ID NO:1175. Applicants reiterate that the level of recited sequence identity in claims 11, 27 and 34 is at least 98%, a level ***far*** above the level of identity recited in Example 14 of the Guidelines, thereby further increasing the required similarity between members of the genus. The present application discloses the species SEQ ID NO:1175 and information relating to variants. Pending claims 11 and 27 also recite that the nucleotide sequence encodes sialophorin.

Applicants respectfully submit that new claims 39 and 40 are also supported by adequate written description and are consistent with claim 1 of Example 10 of the Guidelines. Example 10 provides an example of a process claim, where the specification teaches that SEQ ID NO:10 and "any DNA which hybridizes under specified stringent conditions to SEQ ID NO: 10 will be useful as a marker for detecting the presence of Burkitt's lymphoma." Claim 1 of Example 10 reads "[a] process for producing an isolated polynucleotide comprising hybridizing SEQ ID NO: 10 to genomic DNA in 6XSSC and 65°C..." (see page 38 of the Guidelines). As stated in the analysis of claim 1

> ... the essential feature of the claimed invention is a process of obtaining a nucleic acid sequence which is identified by a probe that hybridizes to SEQ ID NO:10 and a polynucleotide that hybridizes with SEQ ID NO: 10. ... The claim is drawn to a genus ... The specification presents an example where a single species has been reduced to practice ... Therefore the disclosed species within the genus has been adequately described. Now turning to the genus analysis, the art indicates that there is no

> substantial variation within the genus because of the stringency of hybridization conditions which yields structurally similar molecules. The single disclosed species is representative of the genus because reduction to practice of this species, considered along with the defined hybridization conditions and the level of skill and knowledge in the art, are sufficient to allow the skilled artisan to recognize that applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus. ... Claim 1 is adequately described"

(see pages 38 to 40 of the Synopsis of Application of Written Description Guidelines). Consistent with the analysis above, in the instant application, the essential feature of new claims 39 and 40 is that a nucleic acid that hybridizes to SEQ ID NO:1175 under defined hybridization conditions and is useful for diagnosing colon cancer, breast cancer or prostate cancer.

In view of the foregoing, Applicants respectfully request withdrawal of the written description rejection of the claims.

**Rejections under 35 U.S.C. §102**

Claims 10, 11, 20-38 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent Application Publication 2004/0038207A1 (hereinafter "the '8207 publication"). Applicants do not agree.

Preliminarily, Applicants note that claim 10 was cancelled without prejudice, rendering the rejection moot to the extent it applies to claim 10.

The '8207 publication is entitled "GENE EXPRESSION IN BLADDER TUMORS" and compares expression of over 3400 genes in normal urothelium to expression in bladder tumor samples at various stages. However, the '8207 fails to teach or even suggest methods for diagnosing colon cancer, breast cancer or prostate cancer based on comparing expression levels of sialophorin in patient samples of colon tissue, breast tissue or prostate tissue to normal controls, less still correlating an increase of at least 50% in the level of sialophorin in test samples (as compared to controls) to the presence of colon cancer, breast cancer or prostate cancer.

Claims 10 was rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent Application Publication 2007/0037165A1 (hereinafter "the '7165 publication"). The Office alleges that the '7165 publication discloses a sequence (SEQ ID NO:2380) that "is the same as Applicants' SEQ ID NO:1175) and that "the publication also discloses methods of treatment with candidate compounds, drugs or modulators, wherein the said molecules are identified as stimulators or inhibitors of the sialophorin expression". (Office Action page 9). Although Applicants do not agree, solely in an attempt to further the prosecution of the pending claims to allowance, claim 10 has been cancelled without prejudice, rendering the rejection moot.

Claims 10, 11, 20-38 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent Application Publication 2006/0194265A1 (hereinafter "the '4265 publication"). The Office notes that the effective filing date for the '4265 publication is February 27, 2002. Applicants do not agree.

Applicants note that as set forth in MPEP §2136.03, "in order to carry back the 35 U.S.C. 102(e) critical date of the U.S. patent reference to the filing date of a parent application, ..., the parent application must support the invention claimed as required by 35 U.S.C. 112, first paragraph." Upon review of the '4265 publication as well as the claimed priority applications of the 4265 publication, Applicants were unable to find any disclosure of the sequence identified as SEQ ID NO:646 in any of the priority applications with an filing date earlier than that of the present application. Specifically, Applicants reviewed the sequence listings of U.S. patent application Serial Nos.: 10/004,113; 10/052,482; 09/997,722; 10/034,650; and 10/085,117 and were not able to locate a sequence corresponding to SEQ ID NO:646 of the '4265 publication. Accordingly, it appears that the parent application apparently referred to by the Office for purposes of generating an effective filing date (Ser. No. 10/085,117, filed February 27, 2002) does ***not*** support the invention claimed "as required by 35 U.S.C. 112, first paragraph." Applicants respectfully assert that the '4265 publication is not properly cited as prior art against the present application and respectfully request withdrawal of the rejection.

In view of the foregoing, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §102(e).

**Conclusion**

The examination of the pending claims and passage to allowance are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicant invites the Examiner to contact the undersigned at (302) 778-8458 to clarify any unresolved issues raised by this response.

Please apply any charges or credits to Deposit Account 06-1050, referencing Attorney Docket No. 20366-035001.

Respectfully submitted,

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